

REMARKS

Claims 1-5, 7-17, 19-49, and 51-57 are pending in the subject application. Claims 1, 2, 49, and 57 are amended and claim 58 is added. Applicants submit that the amendments herein introduce no new matter, support therefore being found throughout the application and drawings as originally filed.

The Applicants appreciate the Examiner's thorough examination of the subject application and request reconsideration based on the amendments and the following remarks.

1. 35 U.S.C. §102 Rejections

Claims 1-5, 7-11, 19-49, and 51-57 are rejected under 35 U.S.C. §§102(b) over U.S. Patent No. 4,175,704 to Cohen (hereinafter "Cohen"). Applicants respectfully traverse.

Claim 1, as amended, recites a device for the delivery of a substance to the eye comprising a housing for holding the substance, and a non-aerosol, non-electric delivery mechanism comprising a tubular member disposed within the housing, an actuation mechanism positioned at the top of the housing, and at least one outlet port in the actuation mechanism in communication with the tubular member. As set out, the delivery mechanism is configured such that substance is delivered from the housing, through the tubular member, through the outlet port, and to the eye in the form of a spray or mist. As further set out, the outlet port is sized and configured to deliver the spray or mist with a maximum height of 15 mm and a maximum width of 30 mm.

Claim 2, as amended, recites a device for the delivery of an artificial tears or demulcent composition to the eye comprising a housing for holding the substance, and a non-aerosol, non-electric delivery mechanism comprising a tubular member disposed within the housing, an actuation mechanism positioned at the top of the housing, and at least one outlet port in the actuation mechanism in communication with the tubular member. As set out, the delivery mechanism is configured such that substance is delivered from the housing, through the tubular

member, through the outlet port, and to the eye in the form of a spray or mist. As further set out, the outlet port is configured to deliver the spray or mist in an elliptical shape.

Claim 57, as amended, recites, a device for treating the eye comprising a housing holding one or more substances and being free of propellant, a non-aerosol, non-electric delivery mechanism comprising a tubular member disposed within the housing and at least one outlet port in communication with the tubular member. As set out, the delivery mechanism configured such that the substance is delivered to the eye via the tubular member and outlet port in the form of a spray or mist. As further set out, the outlet port is sized and configured to deliver the spray or mist with a maximum height of 15 mm and a maximum width of 30 mm.

Applicants, thus, provide an improved device for delivery of substances to the eye that is designed to overcome the numerous drawbacks of ocular delivery devices. In particular, the device is designed such that no portion of the device contacts the eye, thereby eliminating the risk of ocular surface infections. Further, the device is specifically designed for delivery of the substance to the eye based on the size and geometry of the eye, thereby reducing the likelihood and amount of substance sprayed to areas of the face other than the eye. Still further, the device eliminates the need for a user to tilt the head upwards in an uncomfortable position for delivery. Still further, the device eliminates the need for propellants to deliver the substance to the eye.

Cohen, at least does not teach or suggest a device being configured so as to provide a spray or mist in Applicants' claimed dimensions and geometries. Rather, Cohen provides a device, that when in the form of an ocular delivery device, relies upon an eye cup 60 that projects from the device and is placed into contact surrounding the eye so as to deliver the spray to the eye area.

Thus it is respectfully submitted that claims 1, 2, and 57 are patentable over Cohen. Claims 3-5, 7-17, 19-48, 51-56, and 58 depend from claims 1, 2, and 57 and, thus, also are patentable over Cohen. Reconsideration and withdrawal of the rejection is respectfully requested.

Applicants further recite, in amended claim 49, a method for the delivery of a substance to the ocular surface of a patient comprising providing a non-aerosol, non-electric delivery device housing the substance and comprising a housing, a tubular member disposed within the housing, an actuation mechanism positioned at the top of the housing, and at least one outlet port in the actuation mechanism in communication with the tubular member; positioning the patient's head such that the line of sight is in a generally horizontal direction; positioning device in front of the eye a distance away from the eye without contacting the eye in the line of sight with the housing in an upright position with the actuation mechanism and outlet port positioned at the top of the housing; and delivering the substance to the eye as a spray or mist in a generally horizontal direction.

Cohen, as set out above, describes a device that, when in the form of an ocular delivery device, includes an eye cup 60 that is placed in contact with the face surrounding the eye so as to deliver the spray to the eye. Thus, Cohen does not teach or suggest Applicants' claimed method.

Thus, claim 49 is also patentable over Cohen. Reconsideration and withdrawal of the rejections is respectfully requested.

CONCLUSION

In view of the foregoing, applicant respectfully requests reconsideration, withdrawal of all grounds of rejection and objection, and allowance of claims 1-5, 7-17, 19-49, and 51-58 in due course. The Examiner is invited to contact applicant's undersigned representative by telephone at the number listed below to discuss any outstanding issues.

Respectfully submitted,

Date: September 17, 2008

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